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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,588	01/21/2004	Grigoriy S. Tchaga	CLON-056US2	3721

24353 7590 02/28/2006

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,588	TCHAGA ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13,16,18-21,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13,16,18-21,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This instant office action is in response to (RCE) Request For Continued Examination filed on January 18, 2006.

Claims 11-13, 16, 18-21, and 23-24 are pending and currently under examination. Claims 1-10, 14-15, 17, and 22 are cancelled. Claims 11 and 18 are amended, and claims 23 and 24 are new.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Further, the nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13, 16, 18-21, 23, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 15, 17, 26, and 27 and a specification of copending Application No. 20020164718 A1.

This is a provisional obviousness-type double patenting rejection.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 1, 15, 17, and 26-27 and the teaching from the specification in paragraph [0054] and [0090] of the U.S. 20020164718 A1 fall entirely within the scope of Claims 11-13, 16, 18-21, and 23-24, or in other words, Claims 1, 15, 17, 26, and 27 are

anticipated by Claims 1, 15, 17, and 26-27 and the teaching from the specification in paragraph [0054] of the U.S. 20020164718 A1.

The instant Claims 11-13, 16, 18-21, and 23 and 24 refer to the metal ion chelate resins with hard and intermediate metal ions bound to it peptide, which are used for purification of proteins, where hard and intermediate ions are used, and SEQ ID NO:1 is encoded by nucleic acid in a vector. Claims 1, 15, 17, 26 and 27 refer to a kit for purifying a protein comprising a recombinant vector, which comprises a polynucleotide, which encodes a metal ion affinity peptide depicted in claim 1, and which full sequence is depicted in Figure 3, as Insert 1. Further, the specification states in [0054] that metal ion affinity peptide of the invention has affinity to both hard and intermediate metal ions; where two resins having immobilized thereon a different metal ion: a hard and an intermediate metal ion, can be used with a single metal ion affinity peptide; and in [0090] the reference teaches that recombinant vector comprises a nucleotide sequence encoding a metal ion affinity peptide, and a restriction endonuclease recognition sequence for inserting a heretologous nucleic acid molecule comprising a sequence encoding a fusion partner; where the SEQ ID NO:1 is disclosed in Figure 3.

Therefore, obviousness type double patenting rejection is made against Claims 11-13, 16, 18-21, and 23-24 over Claims 1, 17, 17, 26, and 27 and the relevant paragraphs in the specification of the U.S. 20020164718, because both of the inventions claim the same composition, such as metal chelate resin with intermediate or hard metal ions, and both of the inventions can be used for separation of proteins.

Clearly, the practice of invention of the U.S. 20020164718 would infringe on claims of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-13, 16, 18-21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tchaga et al. WO 99/57992 in view of by Porath et al., "Immobilized Metal Ion Affinity Adsorption and Immobilized Metal Ion Affinity Chromatography of Biomaterials. Serum Protein Affinities for Gel-Immobilized Iron and Nickel Ions," Biochemistry (1983), 22, p. 1621-1630.

Tchaga et al. teach the instant SEQ ID NO:1 in the sequence listing section on page SEQ 7/7, as SEQ ID NO:6. (claims 11, 18, 23, and 24).

Figures 1, 2, and 3 depict the vectors with different restriction sites; and on pages 19 and 20 of the specification the invention teaches recombinant vector comprising DNA sequence where the recombinant vector is capable of directing expression of said DNA sequence for the fusion protein; see claims 1, 2, 6-9 of Tchaga et al.

Further, on page 9 lines 21-24 of the specification, metals that can be used for purification or immobilization of fusion proteins are disclosed and include, Ni(II), Co(II), Zn(II), Cu(II), Ac(III) and Fe(III).

Further, Tchaga et al. teaches different buffers that can be used in the purification of proteins, see Example 4, pages 14 and 15.

Tchaga et al. do not teach two different column/resign that are used in the purification.

Porath et al. teach metal chelate affinity chromatography for purification of serum proteins, where gels are loaded with the same or different metal ion, for example Ni(II) and Fe(III). See *Abstract*.

Porath et al. prepared different columns, for example "IDA-Sepharose 6B" or "TED-Sepharose 4 B" with bound Ni(II) or bound Fe(III), where each chelator gel was packed in a separate column. See page 1622 (*Materials and Methods* section). Different combinations of columns were formed, where two or more columns were packed with one type of chelator gel (e.g., TED-Sepharose) and loaded with different metal ions (e.g., Ni(II) or Fe(III)) to form "tandem columns". See page 1622 (*Chromatography* section). Different combinations of "tandem columns" were created where Fe(III)-TED bed proceeded Ni(II)-TED or Ni(II)-TED bed preceded Fe(III)-TED bed. See page1624 (*Results* section). The following buffers were used for extraction, wash, and elution purposes: 0.05M sodium acetate and 0.1 M NaCl, pH 5.5; 0.1 M Tris-HCl, pH 8.1; 0.5 M sodium acetate, pH 5.5; and 1M glycine, pH 9.0 (Claims 11 and 16).

Therefore, it would have been obvious to one skilled in the art at the time invention was made to design a different resigns as taught by Porath et al. and include in the design a vector as taught by Tchaga et al. because these kind of designs of columns for purification of proteins are known and commonly used in the art in the art.

Relevant Prior Art of Interest:

Chaga et al. "Natural poly-histidine affinity tag for purification of recombinant proteins on cobalt(II)-carboxymethylaspartate crosslinked agarose, Journal of Chromatograpghy A, 864 (1999), p. 247-256, teach SEQ ID NO:1, in Figure 1, page 250, where the purification method is disclosed where single step purification of fusion proteins utilizing artificial poly-histidine tags incorporated on the N- or C-terminus of the protein of interest; where the polyhistidine peptide sequence has very high affinity for immobilized "transition" metal ions; where the cobalt ions immobilized on crosslinked agarose were used for one step purification process; see Figures 1 and 2, pages 248, 250, 252, and 253. The reference only teaches agarose column.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the

organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

ROBERT A. WAX
PRIMARY EXAMINER